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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/964,120
Filing Date: September 25, 2001
Appellant(s): SCHILLING ET AL.

Bernd W. Sandt Reg. No. 19,213
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 23, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

The following rejections are maintained:

A. Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of US patent 4,250,139 to Luck et al in further view of US patent 4,404,033 to Steffan et al.

B. Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,645,851 to Moore in view of JP 59025637.

The following rejections are withdrawn:

The rejection of claim 51 under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of US patent 4,250,139 to Luck et al in view of US patent 4,404,033 to Steffan et al, in further view of JP 59-088065 is withdrawn in view appellant's arguments.

The rejection of claim 51 under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of JP 59025637 in further view of JP 59-088065 is withdrawn in view appellant's arguments.

The rejection of claim 51 under 35 U.S.C. 103(a) as being unpatentable over EP 288405 in view of US patent 5,562,535 to Puppolo, in further view of JP 59-088065 is withdrawn in view appellant's arguments.

The rejection of claims 33-40 under 35 U.S.C. 103(a) as being unpatentable over EP 288405 (abstract) in view of US patent 5,562,535 to Puppolo is withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 42-51 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,645,851	MOORE	7-1997
4,250,139	LUCK et al	2-1981
4,404,033	STEFFAN et al	9-1983
JP 59025637	SATO SUISAN K.K	2-1984

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,645,851 to Moore in view of US patent 4,250,139 to Luck et al in further view of US patent 4,404,033 to Steffan et al.

Moore teaches obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing 5.15% sodium hypochlorite and water to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in 3% hydrogen peroxide to sterilize the cartilage without denaturing the collagen. The product is diced. (Note example 1). The product of example 1 is dried at an average temperature of 110 degrees Fahrenheit to remove over half the water content in example 12. These samples have the advantage of improved shelf life, reduced volume, and better handling.

Moore does not teach adding salt or instant amount of salt.

Luck et al teach a microwave sterilization of dry protein that retains the chemical, physical, and physiological properties of the proteinaceous materials by removing water substantially from the host material. See abstract. Luck teaches a wide variety of proteinaceous material such as instant collagen. Further, the proteins are obtained from sources such as skin, bone, tendons, and cartilage. See column 2, lines 10-20. Luck stresses the importance of ensuring that the protein is unchanged so it retains its activity. See column 2, lines 20-26. Luck et al teach the protein is substantially dehydrated by placing the protein material in an aqueous solution in

combination with salt, which is adventitiously present in the medium. The water is then removed by lyophilization. This drying may be done by freeze-drying, vacuum drying or drying agents to substantially remove the water and preferably to remove all the water. See column 2, lines 31-50. The lyophilization temperature taught is below 75 degrees Celsius (167 degrees Fahrenheit) and preferably below 45 degrees Celsius (113 degrees Fahrenheit). The examples utilize temperatures of 30 or 40 degrees Celsius. See column 3, line 54 and column 4, lines 57.

Steffan teaches the method of making collagen fibers for surgical use. Steffan teaches the use of sodium chloride in the amount of 5 to 15% for dehydration purposes

It would have been obvious to one of ordinary skill in the art a the time the invention was made to combine the teachings of Moore and Luck et al and additionally utilize salt for dehydrating the cartilage. One would have been motivated to do so since Luck et al teach a method of dehydrating protein material by placing the material in an aqueous medium containing salt, followed by lypholization at instant temperatures to remove all the water from the protein material and yet retain the physiological activity of the protein. Therefore, one would have been motivated to further add salt to Moore's method of dehydration to provide for an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material, in order to form a third process for the very same purpose.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to Steffan and utilize the instant amount of salt in Moore's dehydration method. One would have been motivated to do so since Steffan teaches various salts

are utilized to dehydrate collagen fibers, which is optimally utilized at the instant amount. Furthermore, the application of salt in the dehydration of collagen specifically versus cartilage containing collagen would still yield the same result since the function of salt as the drying agent will remain the same.

It is the examiner's position that since the prior art teaches the utilization of instant amount of salt, this will implicitly yield a product with the recited limitation of "at least 45%" salt content in the dried material.

(11) Response to Argument

Appellant argues that although Moore teaches the dehydration of chicken cartilage and retaining its biological activity by preventing denaturization, Moore does not teach the instant temperature, i.e. "below about 110 °F, prevents denaturization. It is further argued that Moore's examples disclose dehydration temperatures of 60 °C (140 °F) and an average temperature of 110 °F. Appellant argues that Moore does not teach the use of an ionizing salt to prevent the denaturization of collagen.

Firstly, it is respectfully pointed out that independent claim 42 does not recite a *specific* dehydration temperature rather it recites, "at a temperature below which denaturization of the Type II collagen occurs". Thus, Moore general teachings clearly meets this limitation since Moore states, "The particulated cartilage is sterilized by means which do not affect or denature the structure of a major portion of the Type II collage in the tissue." See column 2, lines 55-60.

Secondly, the examiner respectfully points to example 12 wherein Moore dries the chicken cartilage in an oven for an average temperature of 110 °F. Dependent claim 44 recites the limitation that heating is conducted at "below **about** 110 °F". Thus, the term "about" permits

some tolerance of about ± 10 degrees. *In re Ayers*, 154 F 2d 182, 69 USPQ 109 (CCPA 1946). Therefore, it is respectfully submitted that under obviousness Moore meets this limitation.

Lastly, the examiner recognizes Moore's deficiency with regard to the salt and hence relies on the secondary reference, Luck et al, to teach this specific limitation. It is also respectfully pointed out that the claims do not recite the use of an ionizing salt "to prevent the denaturization of collagen" as argued by the appellant. The claims merely require salt in the process.

Appellant argues that Luck et al relates to microwave sterilization without alteration of the proteins and teaches that drying may be done with salt. Therefore, appellant argues that Luck does not specifically teach salt improves the drying process or it should be admixed with the protein. It is further argued that Luck et al teaches the use of salt in an aqueous medium.

Firstly, the examiner points out that the appellant is incorrect that Luck et al do not teach mixing the salt with the protein. Luck clearly states "The protein is substantially dehydrated either free of or in combination with salt, which are *adventitiously* present in the aqueous medium." After this process, the water is completely removed by freeze-drying, critical point drying, or vacuum drying. See column 2, lines 34-40. Thus, although Luck states that salt is optional, the reference clearly states it is advantageous to combine the protein with salt during the dehydration process. See column 2, line 36.

Secondly, it is pointed out that Luck teaches a method of preserving protein structure in a protein source by dehydration, such that the protein is free of water to prevent the growth of microorganisms. This process taught by Luck suggests the protein may be dried or alternatively salt may first be mixed with the protein and then dried. Thus, this disclosure in itself

demonstrates the state of the art wherein it is known to combine salt and other drying techniques in a dehydration process.

With regard to appellant's argument that the salt is in an aqueous medium, the examiner points out that this further substantiates the instant rejection. For instance, Moore discloses that the chicken cartilage is 1) washed in a solution of instant antibacterial sodium hypochlorite and *water*, 2) then the cartilage is cut and again soaked in hydrogen peroxide (note that the instant claim language does not exclude additional steps), 3) the cartilage is stored, 4) the cartilage is oven dried at an average temperature of 110 °F. The steps of 1-3 are taught in example 1 and step 4 is taught in example 12. Thus, a skilled artisan would readily recognize that Luck's salts are combined in the step 1 of Moore since Luck and Moore share similar dehydration steps.

Appellant argues that Steffan et al discloses a process for making collagen fibers and not an edible product. Appellant argues that Stefan's process is vastly different from Moore's and Luck's process. It is further argued that the examiner is picking and choosing the teachings of Steffan without regard to the total teachings.

Firstly, Steffan is not only relied upon for its specific teaching of the amount of salt but also to demonstrate the state of the art wherein it is conventional knowledge to use salt as a dehydrating agent. Steffan teaches, "dehydration is achieved with salts such as sodium chloride and sodium sulfate...The optimal concentration of sodium chloride use for dehydration is between 5 to 15 weight percent." See column 3, lines 29-34. Thus, it is the examiner's position that Steffan's teaching is directed to the general mechanism in which sodium chloride works.

Secondly, it is acknowledged that Steffan's teachings are substantially different from Moore and Luck and does not teach an edible product. However, it is respectfully submitted that,

the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Therefore, as discussed above, although Steffan's process is substantially different, the reference is not relied on for the process of dehydration but for it teachings of a generally known and practiced concept that salt acts as a dehydrating agent. It is not the examiner's position that one would pick out an intermediate step of Steffan's, rather it is the examiner's position that a skilled artisan would look at Steffan as establishing the general state of the art wherein salt is a conventional dehydrating agent.

With appellant's argument that Steffan does not teach an "edible product", it is respectfully pointed out that the limitation is not recited in the instant claims and thus it is a moot point.

B. Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,645,851 to Moore in view of JP 59025637.

Moore teaches obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing 5.15% sodium hypochlorite and water to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in hydrogen peroxide to sterilize the cartilage without denaturing the protein. The product is diced. (Note example 1). The product of example 1 can be dried at an average temperature of 110 degrees Fahrenheit to remove over half the water content (example 12). These samples have the advantage of improved shelf life, reduced volume, and better handling.

Moore does not specify the water content. Additionally, Moore does not teach adding salt.

JP teaches treating scallop by dehydrating using salt. JP teaches using 7-15% salt to dehydrate the ligaments of scallops. Note ligaments inherently contain collagen I. Note translation, see page 2.

It would have been obvious to one of ordinary skill in the art a the time the invention was made to combine the teachings of Moore and JP and additionally utilize salt for dehydrating the cartilage. One would be motivated to do so since JP teaches the method of dehydrating ligaments with salt. Therefore, one would be motivated to further add salt to Moore's method of dehydration to provide for an additive effect of further facilitating and hastening the dehydration process. Moreover, it is prima facie obvious to combine two dehydrating techniques taught by the prior art for the same purpose, i.e. drying material containing protein and simultaneously retaining the activity of the material, in order to form a third process for the very same purpose.

Further, one would expect similar results of utilizing salt to dehydrate Moore's cartilage since JP dehydrates ligaments, which contains collagen albeit a different type of collagen then the one instantly clamed. The application of salt in the dehydration of Type I collagen versus Type II does not change the primary function of salt as a dehydrating agent. Salt will nonetheless act in a similar manner of removing water from the material to be dehydrated.

Lastly, it is the examiner's position that since the prior art teaches the utilization of instant amount of salt, this will implicitly yield a product with the recited limitation of "at least 45%" salt content in the dried material.

(11) Response to Argument

Firstly, appellant argues that the ligaments contain Type I collagen and the instant rejection is directed to Type II collagen. Thus, appellant argues there is no motivation to combine the references. Appellant argues that JP does not state that the scallops in JP are maintained in their original condition. Secondly, appellant argues JP does not mention dehydration or the reason to utilize salt. Lastly, appellant argues that although JP utilizes 7-15% salt which is overlapping with instant "at least 15% salt", there is no disclosure that the salt concentration in the product is the same. Appellant argues that the examiner's assertion that the dried product will have the instant salt content is incorrect since the salt content is also affected by the water content of the cartilage. Therefore, it is argued that since the references do not teach dry cartilage, the limitation cannot be implicit.

Firstly, the examiner notes that ligaments contain Type I collagen and the instant invention is directed to Type II collagen. However, JP is not relied upon to teach the dehydration of Type II collagen since the primary reference teaches this limitation. The primary reference, Moore, teaches the dehydration of chicken cartilage containing Type II cartilage, in its active form. The only teaching lacking in Moore is the specific use of salt. Thus, the examiner relies on JP to cure this deficiency only. As set forth in the rejection, the examiner notes the difference between Type I and Type II collagen, however the application of salt in the dehydration of Type I collagen versus Type II does not change the primary function of salt as a dehydrating agent. Salt will nonetheless act in a similar manner of removing water from the material to be dehydrated. It is the examiner's position that JP teaches the general state of the art wherein it is known and conventional to use salt as a dehydrating agent. Thus, JP is relied on to demonstrate

the state of the art and the conventional skills an artisan in the art had at the time the invention was made.

Secondly, the appellant is incorrect in his assertion that JP does not teach salt as a dehydrating agent. The examiner points to page 2, first paragraph wherein JP states that salted scallops are obtained by "dehydrating thin-sliced scallop adductor muscles by using about 7-15% salt." Thus, it is clear that JP's mechanism of dehydration is utilizing salt as the drying agent. Therefore, it is respectfully submitted that a skilled artisan would be further motivated to add salt to Moore's method of dehydration to further facilitate and hasten the dehydration process. It is respectfully submitted that it is prima facie obvious to combine two conventional dehydrating techniques taught by the prior art, i.e. Moore's dehydrating process using heat and JP's dehydrating process using salt, to form a third dehydration technique. It should be further noted that the applicant has not argued the unexpectedness of the instant invention.

Lastly, appellant's assert that the final salt concentration cannot be "at least 45%" since the final salt concentration not only depends on the starting concentration of salt but also if the product is dried. This argument is confusing since this is the premise of the examiner's assertion that the final concentration is implicit. For instance, Moore teaches a dried chicken cartilage and if one were to combine the instant amount of salt as taught by JP, the final salt concentration would be in the same range as appellant's. Thus, appellant's arguments are substantiating the examiner's position that the final salt concentration is implicit.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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SSG
January 7, 2005

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